K082592

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510(k) Summary

LDR Spine USA Easyspine System

1. Owner's Name & Address

LDR Spine USA
4030 West Braker Lane, Suite 360
Austin, TX 78759

Phone: (512) 344-3333
Fax: (512) 344-3350

2. Contact Person

Noah Bartsch MS, RAC,
Manager, Clinical, Regulatory & Quality Affairs
LDR Spine USA
4030 West Braker Lane, Suite 360
Austin, TX 78759

Phone: (512) 344-3319
Fax: (512) 344-3350
Email: noahbartsch@ldrspine.com

3. Date 510(k) Summary Prepared

September 5, 2008

4. Trade Name / Common Name: / Classification:

Trade Name: LDR Spine Easyspine® System

Common Name: Posterior Thoracolumbar Spinal System

Classification:
KWP: Spinal Interlaminal Fixation Orthosis - Class II per 888.3050
MNI and MNH: Pedicle Screw Spinal System - Class II per 888.3070
NKB: Pedicle Screw Spinal System - Class III per 888.3070

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5. **Legally Marketed Equivalent Predicate Devices:**
LDR Spine Easyspine System (K043094)

6. **Device Description**
Easyspine® implants are single use devices for mono-and multi-segmental stabilization of the lumbar and thoracic vertebrae to promote fusion. Easyspine® consists of sacral and pedicle screws, transverse connectors, hooks, and rods of different rigidities. Specialized associated instrumentation is designed for implantation of these devices and for the distraction, compression or reduction of the lumbar and thoracic spine.

7. **Intended Use of the Device**
The LDR Easyspine System is a posterior, noncervical pedicle and non-pedicle system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:

- Degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Trauma (i.e. fracture or dislocation)
- Spinal stenosis
- Deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis)
- Tumor
- Pseudoarthrosis
- Failed previous fusion

8. **Non-Clinical Performance Data**
Mechanical test results demonstrate that the modified Easyspine Transverse Connector design is substantially equivalent to the predicate Easyspine Transverse Connector design, and that the fundamental scientific technology of the device and of the Easyspine System is not changed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 8 2008

LDR Spine USA
% Mr. Noah Bartsch
Manager – Clinical, Regulatory & Quality Affairs
4030 West Braker Lane, Suite 360
Austin, TX 78759

Re: K082592
Trade/Device Name: Easyspine System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: III
Product Code: NKB, KWP, MNH, MNI
Dated: September 5, 2008
Received: September 8, 2008

Dear Mr. Bartsch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K082592

Device Name: LDR Spine Easyspine® System

Indications for Use:

The LDR Easyspine System is a posterior, noncervical pedicle and non-pedicle system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:

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- Tumor
- Pseudoarthrosis
- Failed previous fusion

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082592